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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,955

Applicant(s)

REID ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Objections and Rejections pending since the Office action of March 30, 2006 ("Office action")

1. All previous objections and rejections are withdrawn.

Response to Arguments

2. Applicant's arguments filed June 30, 2006 ("Amendment") have been fully considered but they are not persuasive.

*Rejections of claims 1-3, 5-9, 11, 13, 14, 16, 17, 20, and 21 as being unpatentable
under 35 U.S.C. 103(a) over Urban*

Applicants assert that electrode 1 of Urban does not meet several of the requirements of claim 1 for the at least two conducting layers. See bottom of page 5 of

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the Amendment, bridging to page 6. Assuming *arguendo* that Applicants are correct, these are moot points because the Examiner has not identified electrode 1 as an electrode corresponding to either of the claimed at least two conducting layers. Electrodes 2 and 3 in the embodiments of Figures 11 and 13 of Urban have been identified in the rejections as corresponding to the claimed at least two conducting layers and these electrodes do meet the requirements of the at least two conducting layers.

Rejections of claims 1-3, 5-13, and 16-21 as being unpatentable under 35 U.S.C. 103(a) over Hyland

Applicants appear to assert that the edges in the electrochemical cell of Hyland do not collectively form a wall or walls of the passage. See page 7 of the Amendment. The Examiner respectfully disagrees. Hyland states, "The working electrodes is, for example, in the form of a continuous *band around* the wall(s) of the receptacle," "Furthermore, the step of *creating a hole* in the part containing the working electrode may eliminate the need for a separate step to activate the carbon, or other working electrode," and "This embodiment [Figure 3] of the invention is a *multi-ring* electrode which contains one or more further electrodes 10, 10' in addition to the working, counter and optionally reference electrodes" [emphasis added]." See page 8, lines 10-12;

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page 4, lines 9-11; and page 12, lines 22-25 of Hyland. Indeed, if the conducting layers (electrodes) other the one at the bottom of the receptacle extended into the receptacle as a continuous layer or film they would block sample from flowing to the bottom of the receptacle and contacting all of the electrodes rendering the electrochemical cell inoperative. Applicants also assert that in Hyland the electro-active substance is not in contact with the working electrode. See page 7 of the Amendment. However, as stated on page 8 of the Office action

In Hyland the working electrode is not typically in contact with reagent so the "first electrode" of the previous paragraph would not typically be a working electrode. See bottom paragraph of page 10. However, barring a contrary showing, such as structural or compositional distinctions, the designation of an electrode as a "working" electrode (or counter electrode or reference electrode) is an arbitrary designation only signifying intended use. Hyland discloses that the working electrode and the counter electrode may be made from a variety of materials. The list of materials from which the working electrode may be made is actually included in the list of materials from which the counter electrode may be made. See page 8, second full paragraph and last paragraph, bridging to page 9. Indeed, the working electrode may have an Ag/AgCl layer, which is commonly and traditionally only used for reference electrodes. See page 8, lines 20-23.

Rejections of claims 2, 18, and 19 as being unpatentable under 35 U.S.C. 103(a) over

Urban in view of Fritsch

Applicants' arguments rely in part on their arguments against Urban, which have been addressed above. Applicants also argue, "Fritsch et al. does not disclose or suggest that the cavity electrode system described therein has a working electrode in

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contact with at least one reagent.” See page 8 of the Amendment. However, this was acknowledged in the Office action. Fritsch was only cited for available manufacturing techniques to make the cell volume or dimensions within the claimed ranges. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 5-9, 11, 13, 14, 16, 17, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban (WO 90/12314 A1) ("Urban").

Addressing claim 1, Urban discloses an electrochemical cell comprising an

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insulating substrate (5 in Figures 11 and 13) and a plurality of layers (Figures 11, and 13), the layers comprising at least two conducting layers (2 and 3), wherein one of the conducting layers is a first electrode (2 – top of page 16 and bottom of page 17 and first full paragraph on page 18), and at least two insulating layers (4, 4' in Figures 11, 13), wherein at least one of the at least two insulating layers (Figures 11, and 13) is interposed between the at least two conducting layers (Figure 1), wherein each major surface of each conducting layer is in contact with a major surface of the insulating substrate or a major surface of at least one of the at least two insulating layers (Figures 11 and 13), a passage being formed through the at least two conducting layers and the at least two insulating layers to expose edges of the at least two conducting layers and the at least two insulating layers, the edges collectively forming a wall or walls of the passage, the exposed edges of the at least two conducting layers forming the working electrode and a second electrode of the electrochemical cell (implied by Figures 11 and 13).

As for the first electrode being a working electrode, barring a contrary showing, such as structural or compositional distinctions, the designation of an electrode as a “working” electrode (or counter electrode or reference electrode) is an arbitrary designation only signifying intended use. Furthermore, although the descriptions of Figures 11, and 13 do not label the first electrode (electrode 2) as a working electrode, one with ordinary skill in the art at the time of the invention would understand that it is a working electrode because with regard to related Figure 8 the description of Figure 8 states that the first electrode (electrode 2) is a measurement electrode (top of page 16)

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and with regard to Figures 11 and 13, closely related Figure 2 identifies the first electrode (electrode 2) as a measurement electrode (first full paragraph on page 18) and, in fact, whenever the function of the first electrode (electrode 2) is identified in a description of an embodiment it is identified as a working electrode, while electrode 3 is identified as a counter electrode and electrode 1 as a reference electrode (see, for example, page 14).

As for having the working electrode in contact with at least one reagent, it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because Urban broadly discloses that the electrochemical cell may be used as a biosensor and states, "For this purpose, enzymes are immobilized on one of the electrodes" (page 19, second full paragraph) and since the working electrode will measure the product(s) of the reagent reaction with the sample, by having the reaction layer on the working electrode the response time will be faster and more accurate than if the reaction layer is located elsewhere as the reagent reaction products will have less distance to travel and less chance of being impeded by diffusion effects or chemical interferants.

It should be noted that the examiner has broadly construed the word "contact" in claim 1, especially in the last four lines of the claim, to mean direct or *indirect* contact. In Applicants' embodiments of Figures 1 and 5 a major surface of the working electrode contacts a major surface of the conducting layer or insulating substrate through a reagent layer. In Applicants' Figure 1 note element 20 and for Figure 5 see Applicants' specification page 9, lines 22-27.

Addressing claim 2, for the additional limitations of this claim see Figures 8, 11,
13

Addressing claim 3, for the additional limitations of this claim see Figures 11 and
13

Addressing claims 5-7, for the additional limitations of these claims consider that they are intended uses, which barring a contrary showing, the electrodes in the electrochemical cell of Urban is capable of. The cells in Figures 8, 11, 13 comprise three electrodes: a working electrode (2), a counter electrode (3), and a reference electrode (1). However, the counter electrode is *capable* of being used as a second working electrode to measure the concentration of the same or a different analyte as the other working electrode.

Addressing claims 8, and 9, for the additional limitations of these claims see page 14, second full paragraph (although this passage is in reference to Figures 4 and 5, the intended uses of the these electrodes appears to apply to all of the figures).

Addressing claim 11, for the additional limitations of this claim see Figures 11 and 13.

Addressing claim 13, for the additional limitations of this claim see Figures 11 and 11

Addressing claim 14, for the additional limitations of this claim see Figure 13.

Note that the examiner is broadly construing "irregular shape" to include an electrochemical cell profile with a passage defined by non-parallel walls and a non-monotonically changing spacing between them.

Addressing claims 16 and 17, for the additional limitations of these claims see the last paragraph on page 11. For claim 17 note again, as stated in the rejection of claim 1, "by having the reaction layer on the working electrode the response time will be faster and more accurate than if the reaction layer is located elsewhere as the reagent reaction products will have less distance to travel and less chance of being impeded by diffusion effects or chemical interferants."

Addressing claim 20, for the additional limitation of this claim see Figures 8, 11, and 13. Let the insulating substrate instead be the insulating layer between electrodes 2 and 3, let the top insulating layer 4 and the bottom insulating layer 4 be the at least two insulating layers of claim 1 (after all, an "insulating layer" is also an "insulating substrate").

Addressing claim 21, for the additional limitation of this claim see Figures 8, 11, and 13.

7. Claims 1-3, 5-13, and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyland (WO 03/056319 A2) ("Hyland").

Addressing claim 1, Hyland discloses an electrochemical cell comprising an insulating substrate (bottom layer 7 in Figures 2 and 3 and bottom layer in Figure 7) and a plurality of layers (Figures 2, 3, 7), the layers comprising at least two conducting layers ((5,6,9,10,10') Also see page 12:30 – page13:2, which discloses up to ten electrodes), and wherein one of the conducting layers is a first electrode (6), the first electrode in contact with at least one reagent ((8) Figures 2, 3, and 7), and at least two insulating layers (Figures 2, 3, and 7), wherein at least one of the at least two insulating layers is interposed between the at least two conducting layers (Figures 2, 3, and 7), wherein each major surface of each conducting layer is in contact with a major surface of the insulating substrate or a major surface of at least one of the at least two insulating layers (Figures 2, 3, and 7), a passage being formed through the at least two conducting layers and the at least two insulating layers to expose edges of the at least two conducting layers and the at least two insulating layers, the edges collectively forming a wall or walls of the passage, the exposed edges of the at least two conducting

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layers forming the working electrode and a second electrode of the electrochemical cell (implied by page 8, lines 10-12; page 4, lines 9-11; and page 12, lines 22-25 of Hyland, which discloses band or ring electrodes or a hole through an electrode).

In Hyland the working electrode is not typically in contact with reagent so the "first electrode" of the previous paragraph would not typically be a working electrode. See bottom paragraph of page 10. However, barring a contrary showing, such as structural or compositional distinctions, the designation of an electrode as a "working" electrode (or counter electrode or reference electrode) is an arbitrary designation only signifying intended use. Hyland discloses that the working electrode and the counter electrode may be made from a variety of materials. The list of materials from which the working electrode may be made is actually included in the list of materials from which the counter electrode may be made. See page 8, second full paragraph and last paragraph, bridging to page 9. Indeed, the working electrode may have an Ag/AgCl layer, which is commonly and traditionally only used for reference electrodes. See page 8, lines 20-23.

Addressing claim 2, for the additional limitations of this claim see Figures 2, 3, and 7 and again note page 12:30 – page13:2, which discloses up to ten electrodes.

Addressing claim 3, for the additional limitations of this claim see Figures 2 and 3 and again note page 12:30 – page13:2, which discloses up to ten electrodes.

Addressing claim 5, for the additional limitation of this claim see page 6:1-3 and page 12:20-25.

Addressing claims 6 and 7, for the additional limitations of these claims see page 13, first full paragraph.

Addressing claims 8 and 9, for the additional limitations of these claims see page 12:1-28.

Addressing claim 10, for the additional limitation of this claim see page 12:6-8.

Addressing claim 11, for the additional limitation of this claim see Figures 2, 3, and 7.

Addressing claim 12, for the additional limitation of this claim see page 7, first full paragraph. Let, for example, the passageway have a depth of 50 μm , a length of 0.1 mm, and a width of 0.1 mm (square cross-section from top view). Then the volume will be 500,000 μm^3 , which equals 0.0005 micro liter.

Addressing claim 13, for the additional limitation of this claim see Figures 2, 3, and 7 and page 7, first full paragraph, which implicitly discloses a circular, or square, or rectangular cross-section from a top view.

Addressing claims 16 and 17, for the additional limitations of these claims see page 24:1-11 and

Addressing claim 18, for the additional limitation of this claim see page 22:20-24 – page 23:5.

Addressing claim 19, for the additional limitation of this claim see page 23:10-14.

Addressing claim 20, for the additional limitation of this claim see Figure 2. Let the insulating substrate instead be the insulating layer between electrodes 6 and 9, let the insulating layer between electrodes 5 and 9 be the insulating layer of claim 1 that separates at least two conducting layers, and let the insulating layer directly above electrode 7 be the second of the at least two insulating layers of claim 1.

Addressing claim 21, for the additional limitation of this claim see Figures 2 and 3.

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8. Claims 12, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban (WO 90/12314 A1) ("Urban") as applied to claims 1-3, 5-9, 11, 13, 14, 16, 17, 20, and 21 above and further in in view of Fritsch et al. (US 2003/0015422 A1) ("Fritsch").

Addressing claim 12, although Urban clearly discloses small dimensions for the cell (claim 15 and page 17, last paragraph, bridging to page 18), Urban does not mention a cell volume not exceeding 1 microliter.

Fritsch discloses an electrochemical cell comprising an insulating substrate and alternating layers of conductor and insulator (see the abstract and Figure 6), which also reads on Applicants' claim 1, except for reagent in contact with the working electrode. Fritsch further discloses techniques for making a cell volume down to 0.00000849056 microliter. See paragraph [106], using a circular cavity with a radius of 6.5 μm and a depth of 8 μm .

Barring evidence to the contrary, such as unexpected results, in light of Fritsch, to reduce the electrochemical cell volume in Urban to below 1 micro liter is just scaling down the cell for a smaller expected sample volume range.

Addressing claims 18 and 19, although Urban clearly discloses small dimensions for the cell (claim 15 and page 17, last paragraph, bridging to page 18), Urban does not mention the claimed thickness ranges.

Fritsch discloses an electrochemical cell comprising an insulating substrate and alternating layers of conductor and insulator (see the abstract and Figure 6), which also

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reads on Applicants' claim 1, except for reagent in contact with the working electrode. Fritsch further discloses techniques an embodiment having a cavity with a depth of 8 μm through two conducting layers and two insulating layers. Thus, Fritsch discloses conducting layers and insulating layers that do not exceed 100 micrometers. See paragraph [0106].

Barring evidence to the contrary, such as unexpected results, in light of Fritsch, to have a conducting layer or an insulating layer within the claimed respective ranges is just scaling down the cell for a smaller expected sample volume range.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Primary Examiner
AU 1753
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